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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,677	09/08/2000	Paul O. Sheppard	97-16D1	3635

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EXAMINER	
JAMROZ, MARGARET E	
ART UNIT	PAPER NUMBER
1644	4

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,677	SHEPPARD, PAUL O.	
	Examiner	Art Unit	
	Margaret E Jamroz	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed September 8, 2000 (Paper No. 2), is acknowledged.

Claims 27 and 29-31 are pending and are under consideration in the instant application.

3. Applicant's IDS, filed April 25, 2001 (Paper No. 3), is acknowledged.

4. The abstract of the disclosure is objected to because it does not describe the antibodies claimed in the instant application. Correction is required. See MPEP § 608.01(b).

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.* In addition, Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlink is disclosed in the specification on page 41, line 13. Applicant is required to remove http://.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 27 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds to residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18, which are all human Zsig13, does not reasonably provide enablement for **any** antibody against **any** protein **comprising** residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111 364 of SEQ ID NO: 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make AND/OR use the invention commensurate in scope with these claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims without an undue amount of experimentation. Applicant has not taught how to make any protein comprising residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18 as part of its amino acid sequence to which an antibody could be made.

The term "comprising" is considered open-ended and widens the scope of the claims to include **any** antibody which binds to **any** protein of **any** species which can be **any** protease or **any** protease precursor comprising residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18. Besides the residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18, the specification does not provide guidance as to which other residues are included in the protein **comprising** these sequences.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In the absence of working examples, lack of sufficient guidance, and the breadth of the claims, the changes which can be made in **any** antibody and still specifically bind to **any** protein (which is **any** protease or **any** protease precursor) which has amino acid residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18 as part of its amino acid sequence are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

10. Claims 27 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant does not have an antibody that specifically binds to a protein **comprising** a sequence of amino acid residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15, and residues 1-364 and 111-364 of SEQ ID NO: 18 wherein the protein is a protease or protease precursor as disclosed in the specification on page 3, paragraph 3, and page 4, lines 1-2.

However, the claims as written encompass all types of antibodies of any species which bind to any protein of any species **comprising** amino acid residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18 that vary in length and also in amino acid composition surrounding those described sequences. The instant disclosure of amino acid sequences consisting of residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18 does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. See University of California v. Eli Lilly and Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

There is no description of the required structural, functional, or conserved regions that would be critical to support an antibody against **any** protein **comprising** amino acid residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18. Therefore, applicant has not disclosed sufficient species such that one skilled in the art would conclude that applicant was in possession of the claimed genus of antibodies which specifically bind to a protein comprising amino acid residues 1-373 and 111-373 of SEQ ID NOS: 2 and 15 and residues 1-364 and 111-364 of SEQ ID NO: 18. Applicant has not taught every conceivable protein **comprising** said residues.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Priority

11. Applicant is denied priority to Application No: 09/072,384 and Provisional Application No: 60/044,185.

Disclosure of an antibody which binds to residues 1-373 and 111-373 of SEQ ID NO: 15 and residues 1-364 and 111-364 of SEQ ID NO: 18 was not found in Application Nos: 09/072,384 or 09/062,142 or Provisional Application No: 60/044,185.

The priority of the claims is deemed to be the filing date of the instant application, September 8, 2000.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 27 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,460,953 (A4) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43: 881-886).

The '953 patent teaches monoclonal antibodies against recombinant and wild-type human zymogen protein C (i.e. a protein molecule which is a protease and a protease precursor; see column 1 and column 17, lines 41-47 in particular) comprising the amino acid sequence, Val Leu Thr Ala Ala His Cys, which comprises residues 170-177 of SEQ ID NOS: 2, 15, and 18 of the instant application (see claim 1, lines 35-36 and claim 3, lines 61-63 in particular). Although the reference is silent about the antibody binding to residues 1-373 or 111-373 of SEQ ID NOS: 2 and 15, or residues 111-364 or 1-364 of SEQ ID NO: 18, it does not mean that the reference antibody does not bind to these sequences.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind to residues 1-373 or 111-373 of SEQ ID NOS: 2 and 15 and residues 111-364 or 1-364 or SEQ ID NO: 18 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

As is evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586), that an antibody "cross-reacts", i.e. binds to more than one protein sequence, does not mean that the antibody does not "specifically react" with both proteins. Bost et al. describe antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., Results, page 579).

Similarly, Bendayan (J. Histochem. Cytochem. 1995; 43: 881-886) characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin, and shows that although the antibody is highly specific, it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagons, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the '953 patent anticipates the claimed invention.

14. Claims 27 and 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,712,143, as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43: 881-886).

The '143 patent teaches antibodies to flea serine protease proteins (i.e. SEQ ID NO: 16) comprising the amino acid sequence, Val Leu Thr Ala Ala His Cys Ile, which comprises residues 170-178 of SEQ ID NOS: 2, 15, and 18 of the instant application (see entire document, the Abstract, column 2, lines 2 and 66, and paragraph 2, column 4, line 27, Example 9, and SEQ ID NO: 16, residues 41-48 in particular). Although the reference is silent about the antibody binding to residues 1-373 or 111-373 of SEQ ID NOS: 2 and 15, or residues 111-364 or 1-364 of SEQ ID NO: 18, it does not mean that the reference antibody does not bind to these sequences.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind to residues 1-373 or 111-373 of SEQ ID NOS: 2 and 15 and residues 111-364 or 1-364 or SEQ ID NO: 18 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Bost et al. and Bendayan have been discussed previously. Therefore, the '143 patent anticipates the claimed invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
December 12, 2001

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